540.1004CON2

**UNITED STATES PATENT & TRADEMARK OFFICE**

Examiner: C. A. Azpuru Group: 1615

Re: Application of: Anand R. BAICHWAL, et al.

Serial No.: 10/047,060

Filed: January 14, 2002

For: **CONTROLLED RELEASE INSUFFLATION CARRIER FOR MEDICAMENTS**

## RESPONSE

Assistant Commissioner for Patents
Washington, D.C. 20231

January 30, 2003

S i r:

In response to the Office Action mailed September 27, 2002, applicants request reconsideration of the above-identified application in view of the following remarks.

### Status of the Claims

Claims 26 - 43 are pending.

### I. Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner again rejected claims 26 - 42 under 35 U.S.C. § 112, first paragraph, "*as based on a disclosure which is not enabling*" and also newly rejected claim 43 on the same ground. In response to Applicant's explanation that the disclosure is indeed enabling (see Applicant's Amendment dated August 12, 2002), the Examiner this time asserted that "*for the most part the devices incorporated by reference in the specification are directed to compositions to be delivered and not the devices claimed, with the exception of United States Patent No. 4,590,206.*"

This rejection is respectfully traversed.

From the Examiner's response to Applicant's amendment dated August 12, 2002, (hereinafter "the Amendment"), it appears that the Examiner may not have carefully reviewed either the Applicant's specification or the three device references: WO 92/00771, (hereinafter the '771 reference, disclosing the Bespak device), U.S. Patent No. 2,587,215 (hereinafter the '215 reference, disclosing the Priestly device) and U.S. Patent No. 4,274,403 (hereinafter the '403 reference, disclosing the Struve device), incorporated by reference in Applicant's specification and discussed in its Amendment. First, U.S. Patent No. 4,540,206 cited by the Examiner, is neither incorporated by reference in the application, nor is it discussed as an exemplary inhaler in Applicant's specification or in the Amendment. It is merely disclosed in the background section of the specification, where it is said to be directed to capsules, cartridges or aerosol containers. Second and more importantly, the '771, '215 and '403 references discussed in the Amendment are "for the most part" directed to devices. Compositions are only mentioned as being delivered by disclosed devices and few specifics regarding compositions are detailed.

In view of the Examiner's misreading of the specification and the '771, '215 and '403 references, Applicant believes it now necessary to discuss in detail the portions of the specification describing the Bespak, Priestly and Struve devices. In addition, Applicant finds it necessary to enclose copies of each of these references so that the Examiner can have them close at hand when reading the present Response.

Exemplary medicament delivery devices are described in the specification at pages 19 - 25. Specifically, at pages 20 through 21 of the present specification, the Bespak device is discussed as follows:

> [o]ne such device is known as the Bespak device described in PCT publication WO 92/00771, hereby incorporated by reference, and available from Innovata Biomed Limited. The device described therein includes a storage chamber for storing a powdered drug to be administered and a metering member having metering cups in which individual doses of the powdered drug are placed. Air is inhaled through an inhalation passage at one end of the device and directed into contact with the metering cup that has been filled with the powdered drug. The metering cup is oriented upwardly open to face the air stream and to enable the powder to be released from the cup. Upon inhalation, the dose is mixed with the air flow and

> continues through the mouthpiece to be inhaled.
>
> The metering cups on the metering member are arranged on an outer frusto-conical wall so that each metering cup is positionable to be upwardly open and face the air flow during inhalation. The metering member rotates so that the metering cups move between a position in which the cup receives a dose of the powered drug from the storage chamber to a position in which the cup is exposed to the air flow. As one cup is exposed to the air flow, another cup is aligned with the storage chamber and is being filled with powder. After the dose is blown from the metering cup, and upon subsequent rotation of the metering member, the cup is wiped and cleaned by a wiping element to remove any undispersed powder and then dried via a moisture absorbent material.

The Bespak device is described in even greater detail in the '771 reference, (which was incorporated by reference in the present specification). Applicants specifically point the Examiner to pages 3-13 and Figures 1 through 8b of the '771 reference. Applicant also points out that this device is clearly an inhalation device and that the "composition" contained therein is discussed in no greater detail than as "a substance in finely divided form" (page 3, line 16) or "a drug in the form of micronised powder" (page 8, line 28).

At page 21 of the specification, the Priestly device is detailed as follows:

> [a]nother device for delivery of inhalation powders is described in U.S. Pat. No. 2,587,215 (Priestly), hereby incorporated by reference. Priestly describes an inhaler having a storage chamber containing a powdered medicament, a mixing chamber and means to move a set dose of medicament from the storage chamber to the mixing chamber. The dose is mixed with air in the mixing chamber and inhaled through a mouthpiece.

In the '215 reference (incorporated by reference in the present specification), virtually the entire specification is devoted to description of this device, as are all sixteen Figures. The "composition" contained within this inhaler is described in no greater detail than "the powder carrying parts of this embodiment", (see column 5, line 48) or "the powder to be inhaled", (column 2, line 48).

At pages 21 - 22 of the present specification, the Struve device is specifically discussed as follows:

> [y]et another inhalation device suitable for delivering powdered inhalation drugs is described in U.S. Pat. No. 4,274,403 (Struve), hereby incorporated by reference. Struve describes an inhaler for administering a powdered drug nasally, which includes storage means for containing a quantity of the drug therein. The storage means includes a feed hole through which the powdered drug may be received from the storage means. The device further includes a dispensing head operatively coupled to the storage means for dispensing the powdered drug more nasally. The dispensing head of the Struve inhaler includes a nozzle, a body portion, a dispensing cylinder and a vent means. The nozzle is shaped to be received in the nasal passage of the user. The nozzle includes a dispensing passageway for dispensing the dose into the nasal cavity of patient.
>
> The body portion is located adjacent the nozzle and has a traverse bore therein. The traverse bore operatively connects the dispensing passageway in the nozzle with the feed hole leading to the drug storage means. The feed hole and the dispensing passageway are transversely offset relative to one another at the points where they enter the transverse bore.
>
> The dispensing cylinder includes a metering chamber. The metering chamber may be selectively aligned with either the feed hole or the dispensing passageway. The dispensing cylinder is slidably received in the transverse bore for movement between a first transverse position in which the metering chamber is aligned with the feed hole and a second transverse position in which the metering chamber is aligned with the dispensing passageway. In its first position, the metering chamber can be filled with a charge of the powdered drug when the inhaler is manipulated. In the second position, places the charge of the powdered drug into the dispensing passageway for inhalation by the user.
>
> The vent means is formed as part of the dispensing cylinder and is capable of venting the metering chamber to atmosphere only in the second position of the cylinder, i.e. when the powder disposed in the device such that it may be inhaled by the user.

In the '403 reference, (which is incorporated by reference in the present specification), the Struve device is set forth in six Figures and is described across the entire specification. In the '403 reference, the "composition" is "a powdered medication or drug". The '403 reference further states that "[t]he type of drug being administered is not important to the [Struve] invention and may comprise any drug which is desirably administered to the nasal passages" (column 2, lines 63-66).

Thus, the present specification and the '771, '215 and '403 references provide more than adequate description of the Bespak, Priestly and Struve devices for purposes of enablement, well beyond the Examiner's assertion of merely a basic output port, chamber and actuator. And clearly, each of these references are primarily directed to devices rather than compositions to be delivered.

Independent claim 26 reads as follows:

> 26. A device for delivering a medicament to a patient, comprising
> an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient;
> a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;
> an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port.

In view of pages 19 - 25 of the specification, one of ordinary skill would be enabled to make, use or practice the claimed device set forth in claim 26. As claims 27 - 42 depend from claim 26, these dependent claims are also enabled. Therefore, the Examiner is requested to withdraw his rejection of all of these claims.

Independent claim 43 is a means plus functions claim which reads as follows:

> 43. (New) A device for delivering a medicament to a patient, comprising
> a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;
> means for delivering the cohesive composite to a nasal or oral orafice.

This claim and the present specification, clearly enable one skilled in the art to make and use a device for delivering a medicament to a patient comprising a composite of medicament and a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum and a means for delivering the composite to a nasal or oral orafice. As such, the Examiner's rejection under 35 U.S.C. § 112, first paragraph should be removed.

## II. Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner again rejected claims 26 - 42 and also rejected claim 43 under 35 U.S.C. § 112, second paragraph, "*as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*" In particular, the Examiner asserted that the 35 U.S.C. § 112, second paragraph rejection is maintained because the "*pharmaceutical formulation does not further limit the claimed device.*"

As stated in the Amendment filed on August 12, 2002, independent claim 26 recites a device for delivering a medicament to a patient comprising:

1. an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient;

2. a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from 0.1 to about 125 microns in diameter; and

3. an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port.

Applicant maintains that the Examiner still has not alleged that any of these elements are unclear, but instead apparently objects to the breadth of the claims. An appropriate rejection under 35 U.S.C. § 112, second paragraph has not been set forth and therefore Applicant respectfully requests withdrawal of this rejection. As claims 27 - 42 depend from claim 26 withdrawal of the Examiner's rejection of these claims is also requested.

Independent claim 43 is a means plus function claim which recites:

1. a device for delivering a medicament to a patient, comprising
2. a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising
3. xanthan gum and locust bean gum,
4. wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter; and
5. means for delivering the cohesive composite to a nasal or oral orafice.

The Examiner does not allege that any of these elements are unclear but again seems to object to the breadth of the claim. An appropriate rejection under 35 U.S.C. § 112, second paragraph has not been set forth, and therefore Applicant respectfully requests withdrawal of this rejection.

## III. Rejections under 35 U.S.C. § 102 (b)

The Examiner again rejected claims 26 - 42, and also rejected claim 43, under 35 U.S.C. § 102 (b) as being anticipated by the Burns reference and under 35 U.S.C. § 102 (b) as being anticipated by the Evans reference.

To be anticipated, all the claim limitations of an invention must be found in a single prior art reference. As previously explained in great detail in the Amendment of August 12, 2002, neither the Evans reference or the Burns reference contain cohesive composite particles of medicament and pharmaceutically acceptable carrier wherein the pharmaceutically acceptable

carrier comprises xanthan gum and locust bean gum and the average particle size of said cohesive composite particles is from 0.1 to about 125 microns in diameter. Applicants respectfully re-assert and incorporate by reference, the arguments set forth in the amendment of August 12, 2002.

The Examiner still submits no support for his preemptory conclusion that the pharmaceutical composition is not a proper limitation for independent claims 26 and 43. As such, Applicants respectfully request withdrawal of this rejection. As claims 27 – 42 depend from independent claim 26, withdrawal of the Examiner's rejection of these claims is also requested.

## IV. Conclusion

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if it is determined that any further issues remain.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

Leslye B. Davidson
Reg. No. 38,854

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736 1940